Participation of people with dementia in research

A position paper – 06/01

A. Executive Summary

1. The present paper constitutes the input of Alzheimer Europe and its member organisations to the ongoing discussions about the participation of people with dementia in research and in particular the Council of Europe Convention on Biomedicine and Human Rights and the Draft Additional Protocol to the Convention on Biomedical Research (see relevant articles in annex 1).

2. For the participation of people with dementia in clinical trials, the organisations refers to the specific position paper it has adopted with regard to this question.

3. Alzheimer Europe would like to recall a few general principles which guide this present response:

   a) A diagnosis of dementia does not in itself constitute a lack of legal capacity.

   b) Capacity is not an all or nothing affair. People with dementia should therefore be involved in decisions concerning research even if they are considered "unable to consent".

   c) People with dementia have a right to participate in research, should they so desire.

   d) People with dementia should be encouraged to write advance directives covering the issue of participation in research.

   e) Subject to the fulfilment of certain conditions, a legal representative should be allowed to consent to participate in research on behalf of a person with dementia who is no longer able to consent him/herself (provided that they take into account his/her past and present wishes).

4. On the basis of these principles, Alzheimer Europe has developed the following position with regard to the participation of people with dementia in research:

   a) In the early stages of the disease, people with dementia can themselves consent to research or declare their willingness to participate in research in an advance directive – irrespective of whether such research is likely to entail a direct personal benefit.

   b) A doctor with the relevant expertise and who is not linked to the research should assess the level of capacity of the person with dementia in order to ensure that s/he has sufficient mental capacity to take such a decision and is fully aware of the consequences.

   c) Legal representatives should be able to consent on behalf of people with dementia to participate in research, if the following main conditions are met:

      i. the potential benefit for the person's health is clearly greater than the possible risks;

      ii. the risk of causing discomfort or distress is minimal;

      iii. the research has been approved by an independent ethics committee;

      iv. the same results could not be obtained with other subjects.

v. the legal representative does not benefit financially from the decision.

vi. s/he has been specifically authorised to give consent by a court or the person with dementia.

vii. The necessary safeguards have been taken to protect the privacy of the person with dementia and to respect his/her dignity.

d) In all cases, an independent adviser should be appointed with responsibility for the safety and welfare of the participants.

5. Based on its current information, Alzheimer Europe does not endorse the participation of people with dementia in research WITHOUT a potential benefit for the participants unless the person with dementia decided to participate him/herself and had sufficient capacity to make such a decision. Such decision could have been stated in an advance directive.

B. Introduction

6. Research is extremely important if the care and treatment of people with dementia is to be improved. Research into dementia nearly always necessitates the participation of people with dementia. For this reason, their participation is invaluable. However, respect for fundamental human rights, such as the right to self-determination, the freedom of the individual and the integrity of the human body is equally important and it is essential to obtain the correct balance.

7. Alzheimer Europe has looked at this question in the framework of two successive projects, the first[1] consisting of an inventory of legislation affecting people with dementia in all the Member States of the European Union and the second[2] which aimed at drafting recommendations on how to improve the legal protection and rights of people with dementia.

8. The present discussion paper outlines some of the recommendations of Alzheimer Europe and its member organisations and raises some points, which deserve further clarification and discussion.

C. The necessity for a response by Alzheimer Europe

9. In recent years, the issue of the participation of people with dementia in research has become an increasingly debated topic. Some European countries have already developed legal instruments defining the conditions under which people with dementia may participate in research.

10. These legal provisions differ from one country to another, yet some attempts have been made on a European level to harmonize these rules, most importantly the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of the Council of Europe[3] and the Draft Additional Protocol to the Convention on Human Rights and Biomedicine, on Biomedical Research[4].

11. However, there are numerous different kinds of research, all of which are not covered by existing legislation and rules. For this reason, having already addressed the issue of

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[1] Financed with the support of the European Commission in the framework of their programme of "Actions in favour of people suffering from neuro-degenerative disease, more particularly Alzheimer type (DAT) and related disorders, and their (informal) carers" (SOC 97 201298 05F03)

[2] Financed under the programme of the European Commission of "Support for transnational actions aimed at combating discrimination against elderly and/or disabled people" (VS/1999/022)

[3] Hereafter referred to as the European Convention on Human Rights and Biomedicine

[4] Hereafter referred to as the Draft Protocol on Biomedical Research

participation in clinical trials, Alzheimer Europe would like to widen the debate to cover other kinds of research.

D. General principles

12. At its Annual General Meeting in Munich on 15 October 2000, Alzheimer Europe adopted recommendations on how to improve the legal rights and protection of adults with incapacity due to dementia. These recommendations obviously need to guide any response of the organisation regarding the participation of people with dementia in research.

13. Alzheimer's disease and other forms of dementia are progressive disorders, which may result in a gradual deterioration of a person's ability to function and a subsequent loss of a person's capacity to communicate or make important decisions regarding his/her life.

14. Yet, a diagnosis of dementia does not in itself constitute a loss of the capacity to take such decisions. Thus, the earlier a diagnosis of dementia can be made, the longer a person will be able to participate fully in decisions affecting his/her life.

15. Equally, in order to safeguard people's rights to self determination, it is essential to guarantee that every person diagnosed with dementia has a right to be informed of the diagnosis.

16. Alzheimer Europe would like to encourage newly diagnosed people with dementia to consider drafting advance directives in which they set out their wishes regarding future participation in research.

17. It should be possible for a legal representative to consent to certain research on behalf of a person with dementia who is no longer able to consent subject to the fulfilment of certain conditions.

E. Participation in research

18. The general principles described in the previous section, dictate Alzheimer Europe's response to the question of participation of people with dementia in research.

19. Furthermore, Alzheimer Europe would like to draw a distinction between various situations that might arise when people with dementia are asked to participate in research:

    a) research with people with dementia able to give informed consent

    b) research with people with dementia having expressed their wishes in an advance directive

    c) research with people with dementia unable to give consent **and** without previously expressed wishes

(a) Informed consent

20. As previously mentioned, a diagnosis of dementia does not imply an automatic loss of the person's capacity to take important decisions, such as taking part in research.

21. A great number of people with dementia in the early stages of the disease will be able to fully understand the implications of taking part in research and should therefore be able to give their informed consent.

22. Nevertheless, since the loss of capacity is gradual, the treating doctor should be consulted before the research can go ahead in order to ensure that the person with dementia fully understands the consequences of his/her decision.

(b) Advance directives

23. People with dementia may have expressed their wishes in an advance directive before the onset or in the early stages of their disease. Participation in research may be an issue that was expressly included in such an advance directive.

24. In such cases, wishes expressed in an advance directive can be considered as consent to participation in research. All restrictions or limitations, as to the fields of research that the person is willing to participate in, shall be fully respected.

25. When drafting an advance directive, it would be useful to name a trustworthy person who could be contacted for any issues not specifically covered by the advance directive concerning the agreed participation in research. This could be particularly useful in cases where this person is not a direct relative.

(c) Inability to consent and lack of an advance directive

26. This issue resulted in some controversy amongst the member organisations of Alzheimer Europe. However, all member organisations unanimously agreed on the following conditions for a legal representative to give his/her consent to a person's participation in research:

    a) the potential benefit for the person's health is clearly greater than the possible risks;

    b) the risk of causing discomfort or distress is minimal;

    c) the research has been approved by an independent ethics committee;

    d) the same results could not be obtained with other subjects,

    e) the legal representative has been specifically authorised to give consent by a court or by the person with dementia him/herself;

    f) the interests and the well-being of the adult with incapacity are always placed ahead of the interests of science and society;

    g) the necessary safeguards have been taken to protect the adult's privacy and to respect his/her dignity.

27. Alzheimer Europe endorses the position of the Council of Europe as described in Article 18, paragraphs 1 and 3 of the Protocol on Biomedical Research, but has reservations about paragraph 2.

28. We recognise the importance of carrying out research, which although not directly beneficial to the person with dementia may well be beneficial to other people with dementia at some time in the future. Nevertheless, Alzheimer Europe questions whether it is ethical to subject people with dementia to any kind of research, which does not directly benefit them. On the other hand, Alzheimer Europe also recognises that the notion of direct benefit to take into account the personal satisfaction some people with dementia obtain as a result of feeling useful and needed or the positive effects of increased attention.

29. Consequently, Alzheimer Europe prefers to encourage the use of advance directives as a means of recruiting participants for research which is unlikely to entail direct benefit. A copy of an advance directive is available in all the official languages of the European Union from Alzheimer Europe's offices (145 route de Thionville, L-2611 Luxembourg).

F. Other considerations

30. Consent to research, whether by the person with dementia or his/her legal representative should always be given in writing.

31. At any time during the research, the person with dementia or his/her legal representative should be able to withdraw their consent.

32. Any non-verbal indications by the person of his/her unwillingness continue the research or of discomfort, pain or emotional disturbance should equally be considered as justifiable reasons to discontinue the research, irrespective of the level of incapacity of the person with dementia or whether s/he personally consented in the first place.

33. In case of conflict of interests, when the treating doctor and the doctor in charge of the research are identical, a second opinion by a doctor not implicated in the research should be sought.

34. An independent advisor should be appointed with responsibility for the safety and well-being of the person with dementia. S/he should be suitably informed about dementia and have experience in the form of direct contact with people with dementia in order to be able to recognise signs of suffering/distress even when the person's communication skills have deteriorated somewhat.

35. Further consideration should be given to different kinds and levels of investigation which might not qualify as research *per se* (e.g. that which does not take place in a hospital or institutionalised setting such as observation, manipulation of the environment, surveys and small-scale projects) in order to ensure that the human rights, dignity and privacy of people with dementia are respected, whilst at the same time not discouraging genuine attempts to improve the quality of life or care of people with dementia.

G. Annex 1: The Draft Protocol on Biomedical Research

Article 18 – Protection of persons not able to consent to research

1. Research on a person without the capacity to consent to research may be undertaken only if all the following specific conditions are met:

i) the results of the research have the potential to produce real and direct benefit to his or her health,

ii) research of comparable effectiveness cannot be carried out on individuals capable of consent,

iii) where possible, the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection,

iv) the necessary authorisation has been given specifically and in writing by the legal representative or an authority, person or body provided for by national law, and after having received the information required by Article 19, taking into account previously expressed wishes or objections. An adult not able to consent shall as far as possible taken part in the authorisation procedure. The opinion of a minor shall be taken into consideration as an increasingly determining factor in proportion to age and degree of maturity,

v) the person concerned does not object to participating in the research.

2. Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, subparagraphs ii, iii, iv and v above, and the following additional conditions:

i) the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition,

ii) the research entails only minimal risk and minimal burden for the individual concerned; and any consideration of additional potential benefits of the research shall not be used to justify an increased level of risk or burden.

3. Objection to participation, refusal to give authorisation or the withdrawal of authorisation to participate in research shall not prejudice the right of the individual concerned to receive appropriate and timely medical care.

Article 19 – Information prior to authorisation

Those being asked to authorise participation of a person in a research project shall be given adequate information in a documented and comprehensive form on the purpose, overall plan and methods to be applied in the research project, including the opinion of the ethics committee. They shall also be specifically informed of the items of information listed in Article 16. Where possible , the information shall be provided to the individual concerned.

Article 20 - Interventions with minimal risk and minimal burden

For the purposes of this Protocol, it is deemed that, in terms of the nature and scale of the intervention, the research bears a minimal risk if it is to be expected that it would result, at most, in a very slight and temporary negative impact on the health of the person concerned. It is deemed that it bears a minimal burden if it is to be expected that the symptoms or unpleasantness will be, at the most, temporary and very slight.

In assessing the burden for an individual, a person enjoying the special confidence of the person concerned shall assess the burden where appropriate.